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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,678	02/27/2002	Olivier Schwartz	03495-0217-00000	9442

7590 01/26/2005
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
1300 I Street, N.W.
Washington, DC 20005-3315

EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/083,678

Applicant(s)

SCHWARTZ ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 04 November, 2004, wherein claims 1-23 were canceled and new claims 24-49 introduced. Claims 24-49 are currently under examination.

35 U.S.C. § 112, Second Paragraph

Claims 24-49 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

Claim 24 includes a limitation specifying that the first plasmid encodes "all or a part of a viral genome coding for a viral core" which is vague and indefinite since it is not readily manifest which particular viral structural proteins the claim references. For instance, picornaviruses contain coat proteins and genes required for RNA synthesis. However, they don't contain any "core" proteins per se. Many other viruses have similar virion architectures where they do not display a defined "core". Thus, it is not readily manifest if the claims encompass specific structural proteins (i.e., the Gag coding portion of retroviruses) or other "inner" proteins that do not play a definitive role in virion architecture.

Claim 24 is further vague and indefinite for referencing polypeptides that are "capable of forming viral particles selected

for their fusogenic properties" since the salient characteristics of the polypeptides are not clearly manifest. What are the precise activities of each polypeptide encoded by the nucleic acids present in the immunizing composition? How are the polypeptides "selected" for their fusogenic properties? The disclosure teaches that properly pseudotyped Gag virus-like particles are capable of fusing to antigen presenting cells which results in the processing and presentation of antigen in an exogenous fashion. Appropriate correction is required.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Newly submitted claims 24-49 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The claims are broadly directed toward an immunizing composition comprising two plasmids wherein the first plasmid encodes a "viral core" and the second plasmid encodes a viral envelope or surface protein. The disclosure teaches that nucleic acid compositions encoding pseudotyped HIV-1 Gag virus-like particles are capable of stimulating exogenous antigen presentation pathways by facilitating fusion between the virus-like particle and antigen presenting cell. The only working embodiment set forth in the specification employed the vesicular stomatitis virus glycoprotein (VSV-G) and HIV-1 Gag structural

protein. Appropriate amendment, as supported by the disclosure, of the claim language to reflect this embodiment would be acceptable. However, the claims are not fully enabled for the full breadth of the claim language directed toward any sundry "viral core" protein or viral envelope/surface protein.

The legal considerations that govern enablement determinations pertaining to undue experimentation have been clearly set forth. *Enzo Biochem, Inc.*, 52 U.S.P.Q.2d 1129 (C.A.F.C. 1999). *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988). *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows:

- 1) The disclosure fails to provide adequate guidance pertaining to suitable "viral core" proteins that can reasonably be expected to function in the desired manner. The invention appears to require at the very least, retroviral Gag proteins, that are capable of forming virus-like particles. However, many viruses lack similar structural proteins. Therefore, it is not readily manifest to the skilled artisan what other "core" proteins can reasonably be expected to function in the composition.
- 2) The disclosure fails to provide adequate guidance pertaining to suitable viral envelopes or surface proteins that can be utilized in the claimed compositions. Virion-receptor binding and cell fusion is a specific process that requires a specific interaction

between the viral envelope glycoprotein and a particular cell surface receptor. Cellular coreceptors are also frequently required for cell entry. The invention is based upon the premise that pseudotyped HIV-1 VLPs carrying the VSV-G Env glycoprotein, are capable of fusing to and entering dendritic cells. The VSV-G Env displays a broader host range than most viruses. This is why it was selected to be used in the disclosed composition. However, many other viral envelope-cell receptor interactions are highly specific. The disclosure fails to teach which other cellular receptors are expressed on antigen presenting cells (e.g., dendritic cells) and which heterologous viral envelopes of surface proteins will function as required.

3) The disclosure only provides a limited number of working embodiments as set forth supra involving HIV-1 Gag VLPs pseudotyped with the VSV-G Env.

4) The claims are of excessive breadth and encompass a large genus of viruses with disparate genotypic and phenotypic characteristics. Thus, it is not readily manifest which viral "core" proteins and envelopes/surface proteins will function in the desired manner. Accordingly, when all the aforementioned factors are considered *in toto*, it would clearly require undue experimentation from the skilled artisan to practice the claimed invention.

Finality of Office Action

Applicants' amendment necessitated any and all new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). **A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE**

THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, James C. Housel, can be reached at (571) 272-0902. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

22 January, 2005